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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,807	11/30/2001	Jay Short	DVSA-1005US	6627

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,807

Applicant(s)

SHORT ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34,35,114,115,132-154 and 189-200 is/are pending in the application.
- 4a) Of the above claim(s) 35,132,133 and 136-139 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34,114,115,134,140-154 and 189-200 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of Claims

1. Examiner acknowledges the preliminary amendment filed 04/30/2004.

Claims 31,34,35,114,115,132-154,189-200 are pending.

In response to restriction/election of species requirement, applicant elected peptide SEQ ID No. 2 as peptide species, and self-assembly as way of polymerizing. Claims 35, 132,133,136-139 are withdrawn from consideration as drawn to non-elected species. Claims 31,34,114,115,134, 140-154,189-200 are examined to the extent they are drawn to the elected species.

Claim Objections

2. Claims 152, 153 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.
3. Claim 152: There are two occurrences of the claims. Please correct.

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Sequence Listing

4. The Sequence Listing was approved by STIC for matters of form.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 31,34,114,115,134,140-154,189-200 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 31 (and claims dependent thereupon): The structure of monomeric polypeptide" is not clear: first, the claim defined the polypeptide as having SEQ ID No.2; then, the amendment to the claim continues that the polypeptide "further comprises" various attachments (see end of the claim).

B. Claim 34: It is not clear whether a polypeptide encodes a monomeric polypeptide (e.g., of SEQ ID No. 2) or a conjugate of polypeptide with nucleotide or lipid, as now claimed in the amended version of claim 31.

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C. Claims 134, 135: Again, it is not clear whether the polymer structures addressed in the claims form from polymerization of polypeptide (e.g., of SEQ ID No. 2) or a conjugate of polypeptide with nucleotide or lipid, as now claimed in the amended version of claim 31. Further, in regard to claim 135, it is not clear whether the precise dimensions of peptide tube recited in the claim address any polypeptide or polymer of some particular monomeric polypeptide.

D. Claims 149-152: It is not how attaching of a targeting molecule can be recited as a further step if now amended claim 31 requires that such targeting molecule have already been attached to the monomeric polypeptide before the process of polymerization. Further, the difference in terminology in claims is not clear: claim 31 (and claims 197-200) recite "targeting vector", while claim 150 recites "targeting molecule or vector" .

E. Claim 193: It is not clear whether the polymer comprises nanoscale delivery device or the polymer is, itself, the nanoscale delivery device.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 31,34,114,115,134,140-154,189-200 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention is directed to producing polymers by self-assembly of peptide monomers comprising peptide SEQ ID NO. 2.

The initial question is whether the invention is enabled for producing polymers by self-assembly of peptide SEQ ID NO. 2 itself (rather than monomers comprised of conjugates of this peptide with nucleic acids, lipids, etc). Specification declares in general terms the intention to obtain such polymers. However, there is no evidence that peptide SEQ ID No. 2 is capable of self-assembling into polymers. The only example, example 20 does not describe polymerization of peptide SEQ ID No. 2 itself, but rather describes polymerization of a crude mixture of proteins obtained from E.Coli extract. There is even no evidence that peptide SEQ ID No. 2 is present in the mixture. Further, the example describes polymerization in the presence of unidentified "Polymer Primers" prepared from a "Polymer suspension" (see section (vi) of the

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example - thus, it does not seem to be an example of self-assembly. There is no evidence that the resulting product is a polymer of a peptide (or of one type of peptide) - the example presents results of polymerization as grams protein/grams of E.Coli. The rest of specification lacks guidance on the conditions of polymerization allowing self-assembly of peptide SEQ ID No. 2.

The claims, however, are not drawn to producing polymers by self assembly of SEQ ID No.2 itself; rather, the claims as amended are drawn to producing polymers by self assembly of conjugates of SEQ ID No.2 with such various agents as nucleic acids, lipids, "targeting vectors", and derivatives of the above. Even if there has been demonstration of polymers obtained by self-assembly of peptide SEQ ID No. 2, does not reasonably provide enablement for polymers formed from conjugates of said monomeric polypeptide with lipids or nucleotide derivatives, or "targeting vectors"(e.g., oligosaccharides). It is well known that process of self-assembly of polypeptide monomers into polymers depends critically on the structure of the monomers and even slight changes, such as change in length of chain, or addition of ionized residue may change the rate and/or direction of the reaction. See, for example, Urry et al., or Jenekhe et al. Other than general assertions in the specification, there are no examples in specification of any single polypeptide having an attachment such as lipids or nucleotide derivative, or targeting vector. Nor there is an example of self-

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assembly of any of such peptide conjugates into a polymer (unless one considers as such an example heating a crude extract of E.Coli described in example 20). Nor there is guidance in the specification on polymerization conditions for self-assembly of such conjugate monomers. Much less is there support for self assembly into such structured polymer formation as peptide tubes or nanoscale delivery vehicles, e.g., nanocages.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

7. Claims 134,135 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 193 introduces new matter as it uses the phrase "polymer comprises nanoscale delivery vehicle". Applicants point at p. 13-14 as providing support for such claims language; however, said section of specification describes in general what is a nanoscale delivery vehicle, but does not teach that "polymer comprises nanoscale delivery vehicle.

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Conclusion.

8. No claims are allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

May 14, 2004

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

